

Maryland Health Care Commission

Primary PCI Waiver Application: Initiation of New Program

Supplemental Information

Name of Hospital

Date

1. Provide a general description of the guidelines or standards that the hospital uses or proposes to use for the assessment and care of patients with acute myocardial infarction, including the American College of Cardiology/American Heart Association Guidelines for Management of Patients with Acute Myocardial Infarction and Guidelines for Percutaneous Coronary Intervention.

Indicate whether the hospital is currently accredited as a Chest Pain Center by the Society of Chest Pain Centers.

Chest Pain Center Accreditation _____ Yes _____ No

If yes, date of accreditation _____

2. Provide detailed documentation regarding the proposed logistics for, at a minimum, performing primary percutaneous coronary intervention (PCI) routinely as treatment of choice around the clock, obtaining consent, gathering staff, assuring availability of staff and catheterization laboratory, managing recurrent ischemia or infarction, determining the responsible physician during and after primary PCI, handling failed angioplasty, and handling primary PCI system failure.

3. Describe the current and proposed strategies for managing errors and quality in the hospital's system of care for patients with acute myocardial infarction (AMI).

4. Indicate whether the hospital currently participates in a cardiovascular data registry.

Cardiovascular Data Registry Participation _____ Yes _____ No

If yes, name of registry _____

Dates of participation _____
From (MM/DD/YY) To (MM/DD/YY)

If yes, name of registry _____

Dates of participation _____
From (MM/DD/YY) To (MM/DD/YY)

5. Describe the current policies and procedures governing formal, scheduled cardiac catheterization laboratory (CCL) case review (e.g., determination of need for review, membership of case review team, conduct of case review meeting, minutes/record keeping). Use the tables below to provide a list of the cardiologists, nurses, and technicians who participate in the formal, regularly scheduled meetings, and their attendance at meetings. For applications that are due in or before March of the current year, provide information for the most recent calendar year. For all other applications, provide information for the period from January 1 through the end of the most recent quarter of the current calendar year.

CCL Case Review Meetings – Membership:

Name and Credential	Title
<i>Physicians</i>	
<i>Nurses</i>	
<i>Technicians</i>	

CCL Case Review Meetings – Attendance:

From (Month/Day/Year) To (Month/Day/Year)

[illegible]

6. Describe the current formal program designed to provide staff working in the cardiac catheterization laboratory (CCL) and staff working in the coronary care unit (CCU) with continuing education pertinent to the area. Use the table below to identify three examples of internal (at the hospital, service, or unit level) or external continuing education for staff in each area. If attendance by both staffs is documented, one example may be used to satisfy an educational activity for both. For applications that are due in or before March of the current year, provide information for the most recent calendar year. For all other applications, provide information for the period from January 1 through the end of the most recent quarter of the current calendar year.

Continuing Education Provided to Staff in CCL and CCU:

_____ – _____
From (Month/Day/Year) To (Month/Day/Year)

Care Area	Type/Topic of Activity	Date	Audience	CEU* Approved		Internal Program	External Program
				Y/N	# Credits	Y/N	Y/N

*CEU – continuing education unit of credit. Contact hours of instruction or presentation were in an accredited or approved continuing education course or event.

7. Provide a detailed description of the additional formal training, including the method and length of initial and ongoing instruction, that nursing and technical staff in the CCL and pre- and post-procedure care units must complete to comply with the requirements for a primary PCI program.

8. Use the tables below to describe the availability of each procedure room in the cardiac catheterization laboratory. For applications that are due in or before March of the current year, provide information for the two most recent calendar years. For all other applications, provide information for the period (1) from January 1 through the end of the most recent quarter of the current calendar year, and (2) from January 1 through December 31 of the previous calendar year. Indicate in the space provided for comment whether downtime was attributable to, for example, routine maintenance, equipment repair or upgrade, or lack of staff (specify physician, nurse, technologist).

Availability of Laboratory for Diagnostic Cardiac Catheterization:

To (Month/Day/Year)

CCL Room	Days and Hours of Operation							
	Hours	Mon	Tue	Wed	Thu	Fri	Sat	Sun
	Regular:							
	On-Call:							
	Regular:							
	On-Call:							

CCL Room	Downtime		Comment
	Date (Month/Day)	Duration (Hours)	

Availability of Laboratory for Diagnostic Cardiac Catheterization:

To (Month/Day/Year)

CCL Room	Days and Hours of Operation							
	Hours	Mon	Tue	Wed	Thu	Fri	Sat	Sun
	Regular:							
	On-Call:							
	Regular:							
	On-Call:							

[illegible]

9. Use the table below to indicate for each CCL Room the manufacturer and model number for each essential piece of equipment and when it was installed; note in the comment area the date and type of any significant post-installation upgrades/enhancements.

CCL Room	Equipment Item	Year Installed	Manufacturer	Model	Comment

10. Use the table below to supply information on the staff who currently provide CCL services to AMI patients (as of one week before the due date of the application).

Total Number of Physician, Nursing, and Technical Staff:

(Month/Day/Year)

Staff	Number	Cross-Training (S/C/M)*
Physician		
Nursing	(FTE)	
Technical	(FTE)	

*Indicate whether the nursing staff and technical staff are cross-trained to scrub (S), circulate (C), and monitor (M).

Does the hospital currently have an on-call system in place for CCL personnel?

CCL On-Call System _____ Yes _____ No

If yes, number of CCL on-call teams _____

Use the table below to provide information on the team(s) rotating call.

On-Call CCL Team Staffing, Rotation, and Response Time

Type of Clinical Staff on Team	Number of Staff	Call Rotation*	Response Time^
MD			
Fellow			
RN			
Technologist:			
Other (specify):			

*Specify the frequency and duration of call (e.g., days/week or month, 1700-0700 hours; weekends/month).

^Specify the time established by the hospital's policy for on-call staff to respond to the call (phone, pager). Response time covers the period from receipt of call to arrival at the hospital.

Does the hospital permit the physicians who participate in the on-call schedule to have simultaneous on-call duties for two or more hospitals?

Simultaneous On-Call _____ Yes _____ No

If yes, provide the written policies and procedures that are to be followed when the on-call physician is not available or cannot respond.

11. Use the table below to provide the number of diagnostic cardiac catheterizations performed on inpatients and outpatients. For applications that are due in or before March of the current year, provide information for the two most recent calendar years. For all other applications, provide information for the period (1) from January 1 through the end of the most recent quarter of the current calendar year, and (2) from January 1 through December 31 of the previous calendar year.

Number of Diagnostic Cardiac Catheterizations

Cardiac Catheterization	____/____/____ - ____/____/____ From To		____/____/____ - ____/____/____ From To	
	Inpatient	Outpatient	Inpatient	Outpatient
Right heart				
Left heart				
Combined right & left heart				
<i>Total</i>				

12. Use the table below to provide a breakdown of the number of patients who received thrombolytic therapy. For applications that are due in or before March of the current year, provide information for the two most recent calendar years. For all other applications, provide information for the period (1) from January 1 through the end of the most recent quarter of the current calendar year, and (2) from January 1 through December 31 of the previous calendar year.

Number of Patients Who Received Thrombolysis

<u> / / </u> - <u> / / </u> From To	<u> / / </u> - <u> / / </u> From To
Patients	Patients

Source of data: _____
(e.g., cardiovascular data registry)

13. Use the table below to provide a breakdown of patients by time (in minutes) from hospital arrival to administration of thrombolytic therapy in patients with ST-segment elevation myocardial infarction (STEMI) or left bundle branch block (LBBB) on the electrocardiogram (ECG) performed closest to hospital arrival. For applications that are due in or before March of the current year, provide information for the two most recent calendar years. For all other applications, provide information for the period (1) from January 1 through the end of the most recent quarter of the current calendar year, and (2) from January 1 through December 31 of the previous calendar year.

Time to Thrombolytic Therapy

	<u> / / </u> - <u> / / </u> From To	<u> / / </u> - <u> / / </u> From To
Door-to-Thrombolytic Time	Patients	Patients
≤ 30 minutes		
> 30 minutes		
<i>Total</i>		

Source of data: _____
(e.g., cardiovascular data registry)

14. For a 12-month period that includes the four most recent quarters for which data are available at the time of application, provide the following data from the QIO Clinical Warehouse, AMI quality measures data set, by submitting a data report from the Delmarva Foundation for Medical Care that contains these data:

- Total number of AMI cases submitted to the warehouse for the specified time period

- Total number of AMI cases submitted to the warehouse where the “Initial ECG Interpretation” question has been answered YES
- Total number of AMI cases submitted to the warehouse where the “Initial ECG Interpretation” question has been answered NO

Note: Submit a written request to Delmarva (Mariana Lesher, Director of Data and Analysis) to obtain the data report.

15. Submit a formal, written agreement with a tertiary institution specifying that the tertiary institution agrees to receive, on unconditional transfer, patients for any required additional care, including emergent or elective cardiac surgery or PCI. Identify the tertiary institution that executed the transfer agreement with the hospital.

16. Submit a formal, written agreement with an advanced cardiac life support emergency medical services (EMS) provider that guarantees arrival of the air or ground ambulance within 30 minutes of a request for patient transport by the applicant hospital performing primary PCI without on-site cardiac surgery. Response time covers the period from receipt of call by the EMS provider to arrival at the requesting hospital. Identify the EMS provider with whom the hospital executed the transport agreement.

17. Provide the name and position description of the current physician director of the cardiac catheterization laboratory. Provide the name and position description of the physician who will be responsible for the primary PCI program. Describe the functions and responsibilities, including responsibility for equipment, personnel, physician call schedules, quality and error management, review conferences, credentialing criteria, and termination of privileges.

18. Provide the form for delineation of privileges that each physician requesting privileges in the cardiac catheterization laboratory must complete. Include the current and proposed credentialing criteria for diagnostic and interventional procedures.

List the hospital(s) at which each physician identified in the application has privileges to perform PCI and whether the physician performed PCI procedures at the institution(s) during each of the periods for which data are reported.

19. Use the table below to provide a breakdown of the number of PCI procedures of each interventional cardiologist identified in the application who will request privileges to perform primary PCI at the applicant hospital. For applications that are due in or before March of the current year, provide information for the two most recent calendar years. For all other applications, provide information for the period (1) from January 1 through the end of the most recent quarter of the current calendar year, and (2) from January 1 through December 31 of the previous calendar year.

Number of PCI Procedures Performed as Primary Operator by Physician

[illegible]

20. Provide a timeline, beginning with approval of the waiver, indicating the key tasks in developing the program, their anticipated implementation and completion dates, and when the hospital expects to begin offering the primary PCI service.